

REMARKS

The Office Action mailed June 18, 2008 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 35-36 are canceled by this amendment, the subject matter thereof being presented in new claim 132. Thus, following entry of this amendment claims 1-4 and 120-132 will be pending. Applicants submit that no new matters or issues have been introduced.

Claim Rejections – 35 U.S.C. § 112

Claims 35 and 36 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have canceled claims 35 and 36 herein and presented the subject matter therein in new claim 132. All identified issues under 35 U.S.C. § 112 are believed to have been addressed. Accordingly, Applicants request withdrawal of this rejection.

Claim Rejections - 35 U.S.C. § 102

Claims 35 and 36 stand rejected under 35 U.S.C. § 102(e) as being unpatentable over USPN 6,612,977 to Staskin, et al. (hereinafter, "Staskin"). Applicants respectfully traverse this rejection.

New claim 132 is presented herein with limitations from claims 35 and 36 and is therefore discussed in this section with respect to the rejection over Staskin. Claim 132 includes the feature recited in claim 36 of an introducer needle integrally formed with first and second flat spatulated sections, a flared section, a straight shaft portion, and a curved shaft portion.

The Office Action alleges that Staskin discloses an introducer needle with the claimed features, "where the first flat spatulated section, the flared section, the straight portion, the curved portion, and the second flat spatulated section are integrally formed (i.e., integrated together)." Office Action, p. 3. However, this allegation in the Office Action is not supported by any showing or description in Staskin. In fact, the alleged second flat spatulated section and flared section identified respectively by the Office Action as elements 106' and 54B are not features of the

introducer needle 60, but instead are features of a dilator that is *separate from* the introducer needle. This is clear from the description in Staskin, calling for insertion of the needle into the dilator following securement of the dilator to the sling, sheath or sling assembly. Staskin, col. 20:58-66. Presumably, the parenthetical comment in the Office Action of “integrated together” is provided to support the assertion that the claimed feature of “integrally formed” is found in Staskin. However, even assuming *arguendo* that Staskin supported such an allegation, a *prima facie* case of anticipation would not be established because, at most, Staskin shows and describes connection of the introducer needle to the dilator, as opposed to integral formation thereof.

Accordingly, at least for the reasons set forth above, Applicants respectfully submit that new claim 132 is patentable over the art of record and request reconsideration in view of the rejection of claims 35-36 under 35 U.S.C. § 102.

Claim Rejections - 35 U.S.C. § 103

Claims 1-4, 120-123, 125-128, and 131 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Staskin in view of USPN 4,509,516 to Richmond (hereinafter, “Richmond”). Claim 124 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Staskin in view of Richmond, and further in view of USPN 4,799,484 to Smith, et al. (hereinafter, “Smith”). Claims 129 and 130 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Staskin in view of Richmond, and further in view of USPN 6,755,781 to Gellman (hereinafter, “Gellman”). Applicants respectfully traverse these rejections.

Independent claim 1 recites, *inter alia*, “a first arm pivotally mounted to the central portion and having a first opening at a first end.”

The Office Action alleges that Staskin discloses the features of claim 1, including “a first arm (54B) pivotally connected to the central portion and having a first opening (116).” Office Action, p. 4. Referring to FIG. 12B of Staskin, reproduced below, opening 116 is shown formed through a flat outer surface of a wall that defines one side of slot 110'. According to the specification of Staskin, “one end of the sling 42, sheath 44 or sling assembly 46 is inserted into the slot 110' of the dilator 54B. With the end of the sling 42/sling assembly 46 properly positioned

within the slot 110', the barb 114 of the snap-like element 112' is inserted into the opening 116 of the dilator 54B. The barb 114 is fully seated within the opening 116 when both ridges 120, 122 pass through the opening 116 of the dilator 54B." Staskin, col. 20:26-33.

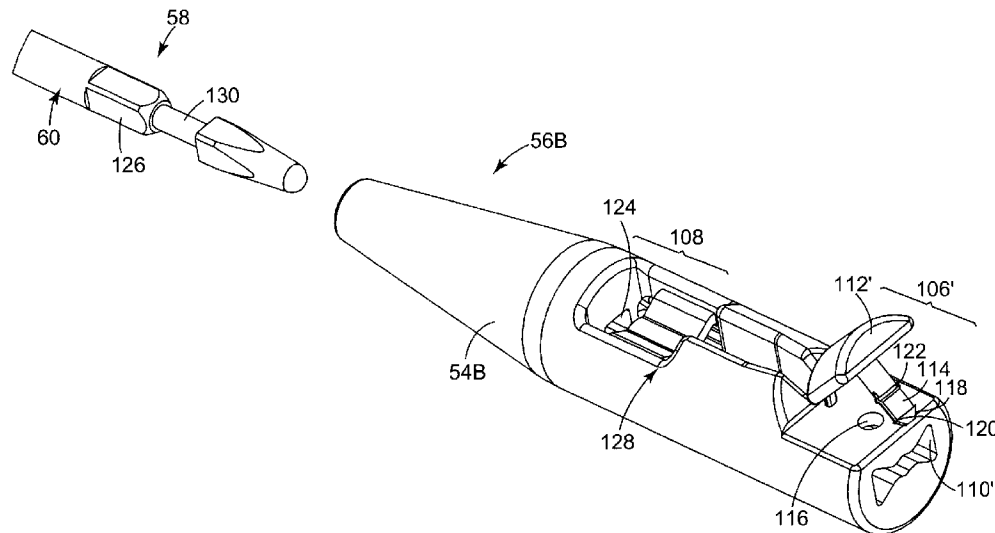


Fig. 12B

From the drawing and description of the interaction between the slot 110', opening 116, and snap-like element 112' it is clear that the surface through which the opening 116 is disposed is *fixed*, as opposed to being *pivotaly mounted* as recited in independent claim 1. Thus, contrary to the allegation in the Office Action, Staskin does not show or describe at least the feature of "a first arm pivotally mounted to the central portion and having a first opening at a first end." Moreover, Richmond fails to supply this feature missing from Staskin as it does not show or describe *any* connector joining the end of the implant member to the flattened portion of the second end of the introducer needle as claimed.

Accordingly, Applicants submit that a *prima facie* case of obviousness is not established by the Office Action at least because the asserted combination does not teach or suggest all of the limitations of independent claim 1. Therefore, Applicants submit that independent claim 1, and claims 3-4, 120-123, 125-128, and 131 depending therefrom, are patentable over the asserted combination of Staskin and Richmond and request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

With respect to claims 124, 129, and 130, without conceding the propriety of the asserted combination, Applicants submit that each depends from patentable independent claim 1, in view of the above. Accordingly, claims 124, 129, and 130 are patentable over the cited combinations and Applicants request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicants of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **50-2191** referencing docket no. 1016760061P. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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